K003488

NOV 2 7 2000

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® Control

1.0 **Submitted By:**

Gail Lefebvre
Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 993-8503
FAX: (714) 961-4123

2.0 **Date Submitted:**

November 8, 2000

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Control

3.2 **Classification Name**

Quality Control Material (21 CFR §862.1660)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Control	SYNCHRON® Control	Beckman Coulter, Inc.	K001458

5.0 **Description:**

The SYNCHRON® Control kit consists of three levels of controls (Levels 1, Level 2, and Level 3) for use on the SYNCHRON Systems. There are a total of 6 bottles (two 20-mL bottles per level). SYNCHRON® Controls are made from stabilized human serum and are designed to monitor the performance of SYNCHRON Systems in the clinical laboratory. SYNCHRON Control serum is prepared from fresh frozen human plasma that has been defibrinated and, then, it is stabilized with ethylene glycol.

6.0 Intended Use:

SYNCHRON® Controls are made from stabilized human serum and are designed to monitor the performance of SYNCHRON Systems in the clinical laboratory. SYNCHRON Control levels, 1, 2, and 3 bear a quantitative relationship to each other; Level 2 is manufactured by combining equal quantities of levels 1 and 3. The use of three levels enable the laboratorian to monitor changes in calibration and linearity along with analytical error and imprecision.

7.0 Comparison to Predicate(s):

The modified SYNCHRON Control claims substantial equivalence to the SYNCHRON Control currently in commercial distribution (K001458). The modified SYNCHRON Control contains acetaminophen and the current product does not.

8.0 Summary of Performance Data:

Stress stability studies of the SYNCHRON Control support the stability claim of 18 months.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 7 2000

Ms. Gail Lefebvre
Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard
M/S W-104
Box 8000
Brea, California 92822-8000

Re: ~~K003~~488
Trade Name: SYNCHRON® Control
Regulatory Class: I reserved
Product Code: JJY
Dated: November 8, 2000
Received: November 13, 2000

Dear Ms. Lefebvre:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~Not yet assigned~~ K003488

Device Name: SYNCHRON® Control

Indications for Use:

SYNCHRON® Controls are made from stabilized human serum and are designed to monitor the performance of SYNCHRON Systems in the clinical laboratory. SYNCHRON Control levels, 1, 2, and 3 bear a quantitative relationship to each other; Level 2 is manufactured by combining equal quantities of levels 1 and 3. The use of three levels enable the laboratorian to monitor changes in calibration and linearity along with analytical error and imprecision.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003488

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

Optional Format 1-2-96